Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the cost-effectiveness of Linezolid compared to vancomycin in the empirical treatment of diabetic foot osteomyelitis: a randomized, controlled clinical trial

Protocol summary

Study aim
The comparison of vancomycin with linezolid regarding the effectiveness and cost in the treatment of diabetic foot osteomyelitis

Design
Two arm parallel group randomized controlled clinical trial. Block randomization will be used for randomization.

Settings and conduct
This study will be a randomized and controlled clinical trial. Patients are selected from different departments of Al-Zahra Hospital in Isfahan. Adults with diabetic foot osteomyelitis are evaluated for inclusion in the study.

Participants/Inclusion and exclusion criteria
Age over 18 years old; hospitalization; diagnosing chronic diabetic foot osteomyelitis based on the presence of pain or tenderness or a sinus with purulent discharge in the area; evidence of osteomyelitis in bone imaging (radiography or MRI) and serum CRP level being higher than the maximum normal value

Intervention groups
Intervention group: linezolid (600 mg IV or PO q12h) + meropenem (1 g IV q8h). Control group: vancomycin (1 g IV q12h) + meropenem (1 g IV q8h)

Main outcome variables
Clinical response (improvement or failure)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150721023282N30**
Registration date: **2025-09-01, 1404/06/10**
Registration timing: **prospective**

Last update: **2025-09-01, 1404/06/10**
Update count: **0**

Registration date
2025-09-01, 1404/06/10

Registrant information
Name
Rasool Soltani
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Isfahan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-23, 1404/07/01
Expected recruitment end date
2026-09-22, 1405/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the cost-effectiveness of Linezolid compared to vancomycin in the empirical treatment of diabetic foot osteomyelitis: a randomized, controlled clinical trial

Public title
Comparison of the cost-effectiveness of Linezolid with vancomycin in the empirical treatment of diabetic foot osteomyelitis: a randomized, controlled clinical trial

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old Hospitalization Diagnosing chronic diabetic foot osteomyelitis based on the presence of pain or tenderness or a sinus with purulent discharge in the area, evidence of osteomyelitis in bone imaging (radiography or MRI) and serum CRP level being higher than the maximum normal value
Exclusion criteria:
The presence of a foreign body at the site of infection Receiving systemic antibiotics in the last 48 hours The presence of osteomyelitis in more than one area The presence of any type of infection in a place other than osteomyelitis sepsis Need for amputation based on the judgment of an orthopedic or infectious disease specialist The need for angioplasty based on the judgment of a vascular, orthopedic or infectious disease specialist
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method is used to assign patients to study groups. For this, blocks size of 4 are used and each patient, after entering the study, is placed in the intervention or control group based on the determined sequence.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Al-Zahra Hospital, Soffeh Ave.
City
اصفهان
Province
Isfehan
Postal code
8174675731
Approval date
2023-10-02, 1402/07/10
Ethics committee reference number
IR.ARI.MUI.REC.1402.166

Health conditions studied

1

Description of health condition studied
Diabetic foot osteomyelitis
ICD-10 code
M86.67
ICD-10 code description
Other chronic osteomyelitis, ankle and foot

Primary outcomes

1

Description
Clinical Response (defined improvement or treatment failure)
Timepoint
End of the second and fourth weeks of intervention
Method of measurement
Clinical judgment by the observation of the patient

Secondary outcomes

1

Description
C-Reactive Protein
Timepoint
End of the first to fourth week of intervention
Method of measurement
Blood test

2

Description
White Blood Count
Timepoint
End of the first to fourth week of intervention
Method of measurement
Blood test

3

Description
Platelet Count
Timepoint
End of the first to fourth week of intervention
Method of measurement
Blood test

4

Description
Acute kidney injury
Timepoint
Every other day until the end of the intervention
Method of measurement
Assessment of serum creatinine

5

Description
Cost
Timepoint
End of intervention
Method of measurement
Calculation of total costs

Intervention groups

1

Description
Intervention group: linezolid (600 mg IV or PO q12h) + meropenem (1 g IV q8h), for 4 weeks
Category
Treatment - Drugs

2

Description
Control group: vancomycin (1 g IV q12h) + meropenem (1 g IV q8h), for 4 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Dr. Rasool Soltani
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Isfahan, Sefeh St., Al-Zahra Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
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Hezar-Jerib Avenue, Isfahan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
professor
Latest degree
Specialist
Other areas of specialty/work
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Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patients data

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available